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Title: VIRTUAL PROTOTYPING AND TESTING FOR
MEDICAL DEVICE DEVELOPEMENT.

Applicant: Whirley and Chobotov
Serial No. 09/679,725 Filed: October 4, 2000
Our Docket No.: 24641-1070

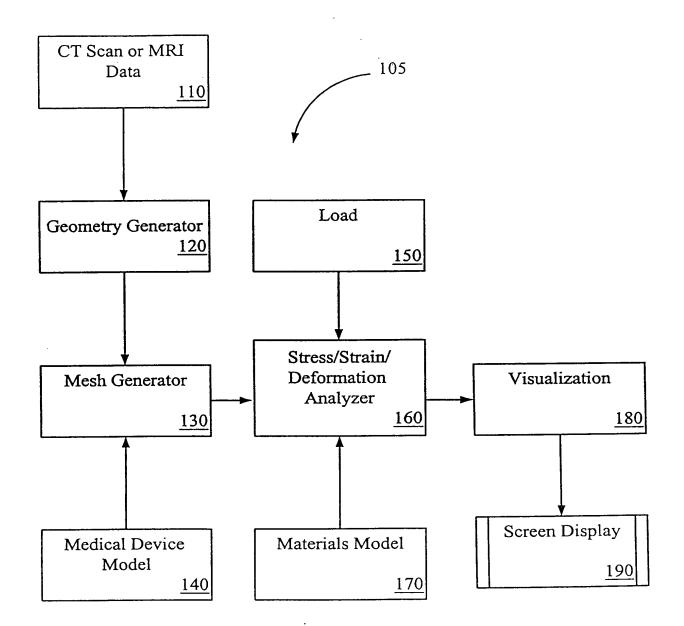
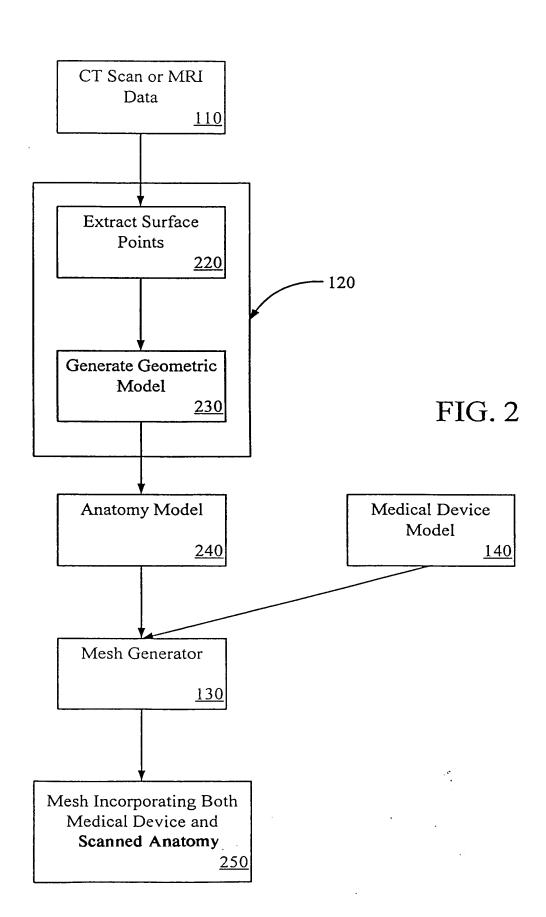


FIG. 1

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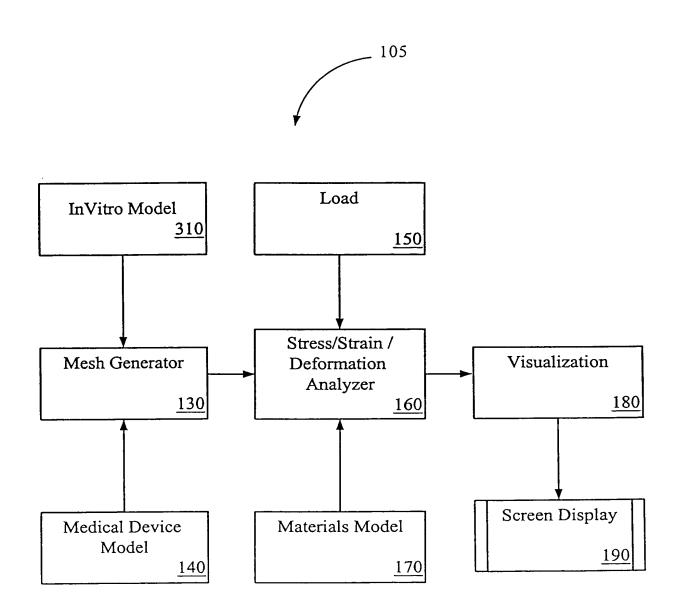
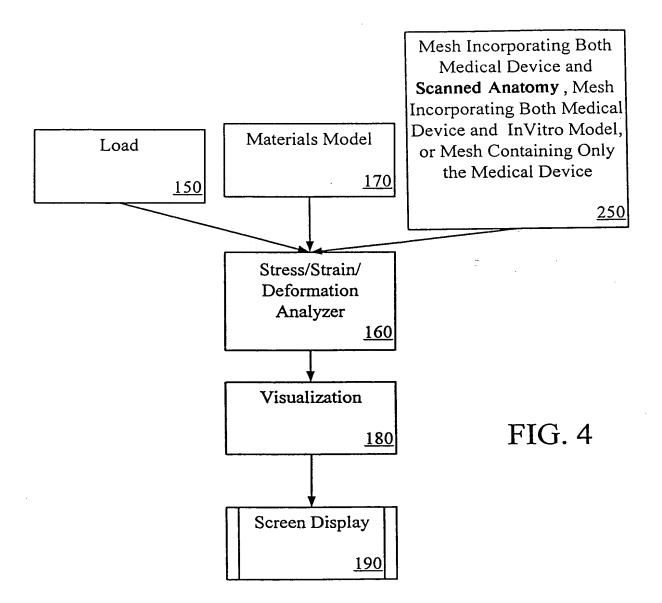


FIG. 3

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FIG. 5A

```
Line Command
    c *** Slotted Tube Integrated Stent Design Simulation: istent.run
2
       ----- parameter settings -----
3
4
    c .... inike=1 => make nike file; inike=0 => make dyna file
5
    c .... imodel = 0 => full 3 segment model with interconnects
7
             = 1 => 3-crown segment only
             = 2 => 6-crown segment only
8
    С
             = 3 => 12-crown segment only
9
     c \dots isym = 0 \Rightarrow full 360 deg model
10
             = 1 => symmetric model
11
     c ... isim mode: type of simulation
12.
            = 1: => radial force to R f = X% R_0, restoring stress mat'l
13
            = 2: => flat plate force, restoring stress mat'l
14
            = 3: => predelivery compression, loading stress mat'l
15
            = 4: => initial expansion
16
            = 5: => frequency analysis
17
     c .... refine = X => add X elements via mseq in each direction
18
                   of the cross section
19
20
21
     parameter inike 1;
     parameter imodel 0;
22
23
     parameter isym 0;
     parameter isim mode 4;
24
25
     parameter refine 2;
26
                            c helps 'tighten' or stiffen spline
27
     para Tighten [0.9];
                     c range (0.5,1) (probably should not change)
28
29
      c ----- parameter settings -----
30
31
32
               ===== design parameters =
33
      c Note: Adjust specified OD for each segment considering the wall
 34
             thickness for that segment so that ID's match in a consistent
 35
             way for the tube blank from which they were cut.
 36
 37
      c Upper segment --- 3 crowns
 38
 39
      c Middle segment -- 6 crowns
```

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FIG. 5B

```
Line Command
     c Lower segment --- 12 crowns (conical)
41
42
     c Parameters for 3-crown segment
43
44
     para
45
      RCyl3 [.5*2/25.4]
        dCIA3 [-.00] c delta of center of inner arc for 3 crown segment (-:0)
46
        dCOA3 [0] c delta of center of outer arc for 3 crown segment (0:+)
47
                       c Circumferential width of segments for 3 crowns
        CW3 [.007]
48
        RW3 [.005] c Radial width for 3 crowns
49
        NRA3 [.0095] c normal radius of smaller cylinders (arcs)
50
                 c for 3 crowns
51
        Ht3 [0.224] c distance from center of upper arcs
52
                  c to center of lower arcs for 3 crowns
53
        NLegEl3 [12]; c number of elements along the leg
54
55
56
     c Parameters for 6-crown segment
57
58
      С
59
      para
         RCyl6 [.5*2/25.4] c outside radius for 6 crown segment
60
                      c delta of center of inner (smaller) arc for 6 crown
61
         dCIA6 [0]
                        segment(-:0)
         dCOA6 [0.002] c delta of center of outer (larger) arc for 6 crown
62
                            segment (0:+)
                       c Circumferential width of segments for 6 crowns
63
         CW6 [.009]
                       c Radial width for 6 crowns
64
         RW6 [.009]
         NRA6 [.0105] c normal radius of smaller cylinders (arcs)
65
66
                  c for 6 crowns
                       c distance from center of upper arcs
67
         Ht6 [.115]
                  c to center of lower arcs for 6 crowns
68
         NLegEl6 [12]; c number of elements along the leg
69
70
71
72
      c Parameters for 12-crown segment
73
      С
 74
      para
                         c delta of center of inner arc for 12 crown segment (-:0)
         dCIA12 [0]
 75
```

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FIG. 5C

```
Line Command
                         c delta of center of outer arc for 12 crown segment
        dCOA12 [0]
76
                               (0:+)
                         c Circumferential width of segments for 12 crowns
        CW12 [.005]
77
        RW12 [.008]
                         c Radial width for 12 crowns
78
                           c normal radius of smaller cylinders (arcs)
        NRA12 [.006]
79
                    c for 12 crowns
80
                         c distance from center of upper arcs
81
        Ht12 [.050]
                    c to center of lower arcs for 12 crowns
82
                    c (measured along the leg, not necessarily in
83
                    c the z direction)
84
        c first outside radius for 12 crown segment (near other segments)
85
        RCyl12_1 [.5*2/25.4 - (.016-%RW12)]
86
        c second outside radius for 12 crown segment (bottom)
87
        RCYl12 2 [.5*1.4/25.4 - (.016-%RW12)]
88
89
     С
        NLegEl12 [10]; c number of elements along the leg
90
91
92
     С
     c Interconnects
93
94
     С
95
96
97
      c Upper interconnects
98
                          c height of interconnect
99
      para HIUp [.02]
                          c fillet radius for blend
100
          FRUp [.005]
                           c circumferential width
          [.006] [CWUp
101
                            c radial width at 3-crown end
          [.005] IRWUp3
102
          IRWUp6 [.006]; c radial width at 6-crown end
103
104
 105
       c S-interconnects
 106
 107
                          c vertical distance between upper or lower arc centers
 108
       para SIVer [.01]
                    c also the distance from the vertical mid-line to
 109
                    c the first arc center
 110
          SIHor [.010] c horizontal distance between upper two or
 111
                    c lower two arc centers
 112
          SIr [.004] c arc radius
 113
```

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FIG. 5D Line Command SIrO [%SIr+%ICWUp/2] c outer radius 114 115 SIrI [%SIr-%ICWUp/2]; c inner radius 116 117 118 c Lower interconnects 119 120 para HILr [.031] c height of interconnect 121 FRLr [.010] c fillet radius for blend 122 ICWLr [.007] c circumferential width 123 IRWLr6 [.005] c radial width at 6-crown end IRWLr12 [.005]; c radial width at 12-crown end 124 125 126 С 127 design parameters 128 129 c set cylinder ID & OD for compression 130 131 if (%isim_mode.le.3) then 132 parameter ricompcyl [1.1*max(%RCyl3,%RCyl6,%RCyl12_1,%RCyl12_2)]; 133 parameter rocompcyl [1.4*max(%RCyl3,%RCyl6,%RCyl12 1,%RCyl12 2)]; 134 135 c set cylinder ID & OD for expansion 136 137 elseif (%isim_mode.eq.4) then 138 parameter rocompcyl [0.95*(min(%RCyl3,%RCyl6,%RCyl12 1,%RCyl12 2)-%RW6)]; 139 parameter ricompcyl [0.7*(min(%RCyl3,%RCyl6,%RCyl12 1,%RCyl12 2)-%RW6)]; 140 endif 141 С 142 С 143 c Materials assignments 144 145 parameter matst12 3; 146 parameter matst6 4; 147 parameter matst3 5;

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FIG. 5E

```
Line Command
      parameter mati126 6;
148
149
      parameter mati63 7;
150
151
152
      if (%isim_mode.eq.1) then
        echo *** Radial Force Simulation ***
153
      elseif (%isim mode.eq.2) then
154
        echo *** Flat Plate Force Simulation ***
155
      elseif (%isim mode.eq.3) then
156
        echo *** Predelivery Compression Simulation ***
157
      elseif (%isim mode.eq.4) then
158
        echo *** Initial Expansion Simulation ***
159
      elseif (%isim mode.eq.5) then
160
        echo *** Natural Frequency Analysis ***
161
162
      else
163
        echo !!! ERROR: illegal isim_mode !!!
164
        interrupt
      endif
165
166
167
      c ----- analysis options -----
      title stent initial expansion simulation
168
169
          *** DYNA3D Analysis Options ***
170
171
172
      if (%inike.eq.0) then
       echo Making DYNA3D input file
173
174
       dyna3d
        dynaopts
175
        term 5.0e-5
176
        plti 1.e-6
177
178
        prti 5.0e-6
179
180
      c .... DR options
181
182
       itrx 500
       tolrx 1.0e-2
183
184
       drdb
185
       c .... thermal effects option - temp from load curve 1
186
```

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FIG. 5F

```
Line Command
187
      С
188
       teo 1
189
190
      tssf 0.0
191
192
      c print initial time step size
193
194
      c prtflg 1
195
196
      c .... turn off (0) or on (1) SAND database flag
197
198
       edsdf 0
199
200
       nrest 90000
201
       nrunr 95000;
202
203
      c .... DYNA3D discrete nodes impacting surface - stent to cyl
204
                  * one side (180 deg) *
205
206
      sid 1 dni
207
      c sfif
208
      c mfif
209
      pnlts 1.0e-0
210
      pnltm 1.0e-0
211
212
      С
213
      c .... DYNA3D discrete nodes impacting surface - stent to cyl
214
                  * opposite side *
215
216
      c sid 2 dni
      c sfif
217
218
      c mfif
219
      c pnlts 1.0e-4
220
      c pnltm 1.0e-4
221
      c ;
222
223
      c .... end DYNA3D commands
224
225
      endif
```

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```
Line Command
                                                              FIG. 5G
226
      С
227
      С
          *** NIKE3D Analysis Options ***
228
      С
229
230
      if (%inike.eq.1) then
       echo Making NIKE3D input file . . .
231
232
       nike3d
233
       nikeopts
234
        nstep 5
235
        delt 0.2
236
        anal stat
237
238
      c .... step tol of 1e-8 seems OK for predel compression
239
      if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
240
241
        dctol -1.0e-8
      elseif (%isim_mode.eq.3) then
242
243
        dctol -1.0e-6
244
      endif
245
246
      c .... max iterations per stiffness reform
247
        nibsr 20
248
249
250
      c .... max stiffness reforms per step
251
252
        msrf 20;
253
254
       c .... temperatures follow load curve 1
           ** manually add tref=1.0 on matl 2 control card cols 26-35 **
255
256
257
        teo 1
258
       if (%isim mode.eq.1.or.%isim mode.eq.2) then
259
260
       elseif (%isim mode.eq.3.or.%isim mode.eq.4) then
261
        iprt 25
262
       endif
263
        iplt 1
264
        nsbrr 1
```

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```
Line Command
265
        stifcore 1
                                                                 FIG. 5H
266
        bfgscore
267
        bwmo new
268
        echo Bandwidth minimization ACTIVATED with "NEW" option
269
270
      c element constitutive data incore
271
272
        bfor 10
273
        sfor 10
274
        bef 11
275
      c .... linear solver
276
277
       Isolver fissle
278
279
280
      c .... solid element stent contact surface
281
282
      sid 1 sv
283
284
      if (%isim mode.eq.1) then
285
286
       pnlt 1.0e-5
287
288
      elseif (%isim mode.eq.2) then
289
       pnlt 0.00001
290
      elseif (%isim mode.eq.3) then
291
292
      c .... essential to adjust penalty
293
294
      pnlt 1.0e+4
      elseif (%isim mode.eq.4) then
295
296
       pnlt 1.0e-5
297
      ciaug 1;
298
      endif
299
300
301
      c .... slidesurface between interconnects and segments
302
      sid 2 tied
303
```

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```
Line
      Command
304
                                                                  FIG. 5I
305
      С
      c .... NIKE3D shell geometric stiffness (HL only)
306
307
308
       segs 1;
309
      c .... end NIKE3D section
310
311
312
      endif
313
314
      c .... symmetry planes
315
316
      if (%isym.eq.1) then
317
318
      c .... Symmetric Model
           theta=-60 and +60 symmetry to remove rigid body modes
319
320
      С
321
      c plane 1
      c 0.0 0.0 0.0
322
323
      c [-\sin(60)][-\cos(60)] 0.0
324
           0.0005 symm;
325
       c plane 2
326
       c 0.0 0.0 0.0
       c [-\sin(60)] [\cos(60)] 0.0
327
328
           0.0005 symm;
329
       С
330
       else
331
       c .... symmetry planes to remove rigid body modes for full model
332
333
334
       plane 1
335
        0.0 0.0 0.0
336
        1.0 0.0 0.0
337
         .0005 symm;
338
       plane 2
 339
        0.0 0.0 0.0
        0.0 1.0 0.0
 340
 341
          .0005 symm;
       c plane 3
 342
```

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```
Line Command
      c 0.0 0.0 0.0
343
                                                               FIG. 5J
      c 0.0 0.0 TBD
344
345
          .0005 symm;
346
      endif
347
      С
348
      if (%inike.eq.0) then
349
350
      c .... Load Curves for DYNA3D **ADD DR FLAG TO INPUT FILE **
351
352
353
      if (%isim_mode.eq.1) then
354
355
      c .... radial force
356
357
      lcd 1
358
         0.000E+00 1.000E+00
359
         7.500E-03 2.250E+04
         1.000E-00 2.250E+04;
360
      c 1.000E-02 3.000E+04
361
362
      c 1.000E-00 3.000E+04;
363
      elseif (%isim_mode.eq.2) then
364
      c .... flat plate compression, lcd 1 not used (dummy definition)
365
366
      С
367
      quit
368
369
      elseif (%isim mode.eq.3) then
370
371
      c .... predelivery compression strain
372
373
      lcd 1
374
         0.000E+00 1.000E+00
         1.000E-02 2.008E+05
375
376
         1.000E-00 2.008E+05;
377
      endif
378
      c .... load curve #2 only used for flat plate compression
379
380
      С
381
      lcd 2
```

FIG. 5K

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```
Line Command
382
        0.000E+00 0.000E+00
383
        1.000E+00 0.000e-00;
      endif
384
385
386
      if (%inike.eq.1) then
387
      c .... ****** Load Curves for NIKE3D *******
388
389
390
      if (%isim mode.eq.1) then
391
392
      c .... radial force
393
394
      lcd 1
395
         0.000E+00 1.000E+00
         1.000E+00 2.000E+03;
396
397
      elseif (%isim mode.eq.2) then
398
399
      c .... flat plate compression
400
401
      lcd 1
402
         0.000E+00 1.000E+00
403
          1.000E+00 0.000E+00;
404
      elseif (%isim_mode.eq.3) then
405
406
      c .... predelivery compression strain
407
408
      lcd 1
409
         0.000E+00 1.000E+00
          1.000E+00 2.008E+03;
410
411
      elseif (%isim mode.eq.4) then
412
413
      c .... initial expansion strain
414
415
      lcd I
      c .... thermal load (activate TEO above)
416
417
      c 0.000E+00 1.000E+00
          1.000E+00 -2.008E+04;
418
419
      c .... prescribed displacement
420
          0.000E+00 0.000E+00
```

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```
Line
      Command
         1.000E+00 1.000E-02;
421
                                                                FIG. 5L
422
      endif
423
      С
424
      c ----- stent parts -----
425
426
      include irss.tg
427
428
      c ----- stent materials -----
429
430
      if (%inike.eq.1) then
           if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
431
432
             include istent.mats_nike_solid
              echo model for radial force/flat plate analysis
433
434
           elseif (%isim mode.eq.3) then
435
              include istent.mats_compress_nike_solid
              echo model for predelivery compression strain
436
           elseif (%isim mode.eq.4) then
437
438
              include istent.mats compress_nike_solid
              echo model for initial expansion strain
439
440
           endif
441
442
      elseif (%inike.eq.0) then
           if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
443
              include istent.mats dyna solid
444
              echo model for radial force/flat plate analysis
445
446
           elseif (%isim_mode.eq.3) then
              include istent.mats compress dyna_solid
447
              echo model for predelivery compression strain
448
            elseif (%isim mode.eq.4) then
449
              include istent.mats compress_dyna_solid
450
              echo model for initial expansion strain
451
            endif
452
453
      endif
454
      С
      c .... cylindrical compression for radial force or predelivery compression
455
456
      if (%isim_mode.eq.1.or.%isim_mode.eq.3.or.%isim_mode.eq.4) then
457
458
459
         if (%isym.eq.1) then
```

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Line	Command
460	include cylinder.parts_sym
461	else
462	include cylinder.parts
463	endif
464	c
465	if (%inike.eq.1) then
466	include cylinder.materials_nike
467	elseif (%inike.eq.0) then
468	include cylinder.materials_dyna
469	endif
470	endif
471	c
472	stp .01
473	merge
474	C

FIG. 5M

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```
****** TPEG Inflatable Proximal Seal Simulation **********
1
2
                       (seal.run)
       С
                                                                          FIG. 6A
                       March, 1999
3
       С
4
5
       c ----- parameter settings -----
6
7
       c .... analytical model aorta geometric parameters
8
             (distortion is 4-lobe)
9
       С
10
       parameter r aorta [10.0/25.4];
11
       parameter thk aorta [1.0/25.4];
       parameter amp_plaque [0.0/25.4];
12
13
14
       parameter ro_aorta [%r_aorta+%thk_aorta];
15
16
       c .... - TPEG Design Parameters --
17
18
       parameter r tpeg [10/25.4];
19
       parameter r_ps [3/25.4];
       parameter 1_tpeg 2.0;
20
21
       parameter l_flap 0.25;
22
23
       parameter graft wall thick [6*0.0013];
       parameter cuff_wall_thick [3*0.0013];
24
25
       parameter flap wall thick [6*0.0013];
26
       С
27
28
       c .... Pressures and load curve assignments
29
30
       parameter P hemo 2.32;
       parameter P cuff 3.0;
31
32
33
       parameter lc hemo 1;
34
       parameter lc_proxcuff 3;
35
36
       c .... TPEG folding simulation parameters
37
38
       parameter vel_fold 20.0;
39
       parameter t fold [0.25/%vel fold];
40
       parameter t_init 0.0e-3;
```

41

42

С

C

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```
43
       c ----- analysis options -----
       title sc6.i Seal CT-Solid r_t=10mm r_ps=3mm P_cuff=3.0 990428
44
45
46
            *** DYNA3D Analysis Options ***
       С
                                                                    FIG. 6B
47
       С
48
       dyna3d
49
       dynaopts
        term 6.5e-2
50
51
        plti 5.e-4
52
        prti 2.5e-2
53
54
       c .... DR options
55
56
       itrx 500
57
58
       c .... increase DR tol to prevent convergence after compression before expansion
59
60
       c tolrx 1.0e-6
61
       tolrx 1.0e-12
62
       drdb
63
64
        tssf 0.9
65
66
       c .... turn off (0) or on (1) SAND database flag
67
       c
68
         edsdf 0
69
70
        nrest 90000
        nrunr 5000;
71
72
73
       c .... symmetry planes on xz and yz planes
74
75
       plane 1
76
         0.0 0.0 0.0
77
         1.0 0.0 0.0
                     0.001 symm;
78
       plane 2
79
         0.0 0.0 0.0
        0.0 1.0 0.0 0.001 symm;
80
81
82
       c .... DYNA3D slidesurface: +x folder cylinder
83 .
       sid 1 sv
84
```

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```
85
        pnlts 1.0
                                                                FIG. 6C
86
        pnltm 1.0
87
        pen
88
89
90
        c .... DYNA3D slidesurface: -x folder cylinder
91
92
        sid 2 sv
93
        pnlts 1.0
94
        pnltm 1.0
95
        pen
96
97
        С
98
99
        c .... DYNA3D slidesurface: +y folder cylinder
100
101
        sid 3 sv
102
        pnlts 1.0
103
        pnltm 1.0
104
        pen
105
106
107
        c .... DYNA3D slidesurface: -y folder cylinder
108
109
        sid 4 sv
110
        pnlts 1.0
111
        pnltm 1.0
112
        pen
113
114
115
        c .... DYNA3D tpeg to aorta (aorta is master)
116
        С
117
        sid 5 sv
118
119
        c .... solid element aorta
120
121
        pnlts 0.1
122
        pnltm 0.1
123
124
        c .... shell element aorta
125
126
        c pnlts 1.0
```

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```
127
       c pnltm 1.0
                                                                       FIG. 6D
128
       pen
129
       ;
130
       c .... load curve: hemodynamics **** ADD DR FLAG TO INPUT FILE ****
131
132
133
       lcd 1
134
        0.000E+00
                            0.000E+00
135
        [%t init+2*%t fold+1.0e-3] 0.000e+00
136
        [%t init+2*%t_fold+2.0e-3] %P_hemo
137
        1.000E+00
                            %P_hemo;
138
       С
139
       c .... load curve: channel !! NOT USED !! **** ADD DR FLAG TO INPUT FILE ****
140
141
       lcd 2
142
        0.000E+00 0.000E+00
143
        [%t init+2*%t_fold+1.0e-3] 0.000e+00
144
        [%t init+2*%t_fold+2.0e-3] 0.000e-00
        1.000E+00
145
                             0.000e-00;
146
       c .... load curve: proximal cuff **** ADD DR FLAG TO INPUT FILE ****
147
148
       C
149
       lcd 3
150
        0.000E+00 0.000E+00
151
        [%t_init+2*%t_fold+1.0e-3] 0.000e+00
152
        [%t_init+2*%t_fold+2.0e-3] %P_cuff
153
        1.000E+00
                             %P_cuff;
154
155
       c .... load curve for +x folder cylinder motion/velocity
156
157
       lcd 4
                              0.000E+00
158
        0.000E+00
                            0.000E+00
159
        %t init
                                 [-%vel fold]
160
        [%t_init+1.0E-04]
                                 [-%vel_fold]
161
        [%t_init+%t_fold]
162
                                    0.000E+00
        [%t_init+%t_fold+1.0e-3]
163
        [%t init+2*%t fold+1.0e-3]
                                     0.000e+00
164
        [%t_init+2*%t_fold+2.0e-3]
                                     [2.0*%vel fold]
165
        [%t_init+3*%t_fold+2.0e-3]
                                     [2.0*%vel fold]
166
        [%t init+3*%t fold+3.0e-3]
                                     0.000e+00
167
        1.000E+00
                        0.000E+00;
168
       ¢
```

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```
c .... load curve for -x folder cylinder motion
 169
                                                              FIG. 6E
 170
 171
        lcd 5
 172
         0.000E+00
                                 0.000E+00
                              0.000E+00
 173
         %t init
         [%t init+1.000E-04]
                                    [ %vel_fold]
 174
         [%t_init+%t fold]
                                   [%vel fold]
 175
         [%t_init+%t_fold+1.0e-3]
                                      0.000E+00
 176
 177
         [%t init+2*%t fold+1.0e-3]
                                       0.000e+00
         [%t init+2*%t_fold+2.0e-3]
                                       [-2.0*%vel fold]
 178
                                       [-2.0*%vel fold]
 179
         [%t_init+3*%t_fold+2.0e-3]
                                       0.000e+00
 180
         [%t init+3*%t fold+3.0e-3]
                                 0.000E+00;
          1.000E+00
 181
 182
 183
        c .... load curve for +y folder cylinder motion
 184
 185
        lcd 6
          0.000E+00
                                 0.000E+00
 186
                               0.000E+00
 187
          %t init
          [%t init+1.000E-04]
                                    [-%vel_fold]
 188
          [%t_init+%t fold]
                                   [-%vel fold]
 189
 190
          [%t_init+%t_fold+1.0e-3]
                                      0.000E+00
                                       0.000e+00
.. 191
          [%t init+2*%t fold+1.0e-3]
          [%t init+2*%t fold+2.0e-3]
                                       [2.0*%vel fold]
 192
 193
          [%t init+3*%t_fold+2.0e-3]
                                       [2.0*%vel fold]
 194
          [%t init+3*%t fold+3.0e-3]
                                       0.000e+00
          1.000E+00
                                 0.000E+00;
 195
 196
         C
 197
         c .... load curve for -y folder cylinder velocity
 198
         С
 199
         lcd 7
                                 0.000E+00
 200
          0.000E+00
                               0.000E+00
 201
          %t init
                                    [%vel fold]
          [%t init+1.000E-04]
 202
                                   [ %vel_fold]
 203
          [%t init+%t fold]
          [%t_init+%t_fold+1.0e-3]
                                      0.000E+00
 204
          [%t init+2*%t fold+1.0e-3]
                                        0.000e+00
 205
         [%t init+2*%t_fold+2.0e-3]
                                       [-2.0*%vel fold]
 206
          [%t init+3*%t fold+2.0e-3]
                                        [-2.0*%vel fold]
 207
                                        0.000e+00
 208
          [%t_init+3*%t_fold+3.0e-3]
          1.000E+00
 209
                                 0.000E+00:
 210
```

С

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```
c ----- parts and materials -----
211
                                                                             FIG. 6F
212
       С
213
       С
        c .... get CT-data meshed aorta; convert cm to inches
214
215
        csca [1./2.54]
216
        include tpeg.part_ct_aorta3
217
218
        csca 1.0
219
220
        c .... option for analytical aorta model
221
222
223
        c include tpeg.part_eq_aorta
224
225
        include tpeg.part_cuffl
226
        include tpeg.part_folder2
227
228
        include tpeg.materials dyna
229
        c .... use negative tols to prevent aorta nodes merging w/ folder cylinder
230
             nodes if they coincidently become adjacent
231
232
233
        c .... merge nodes within CT aorta part using rather loose tolerance
234
235
        bptol 1 1 0.01
        bptol 1 3 -1.0
236
        bptol 1 4 -1.0
237
        bptol 1 5 -1.0
238
        bptol 1 6 -1.0
239
        tp .001
240
241
```

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Aortic Model for Inflatable TPEG Model -----

6 c Derived from Patient CT Data
7 c Outer surface constructed with 0.52 mm offset from inner
8 c

9 c this is an aortic mesh file which surrounds the neck of the 10 c 3-D AAA reconstruction with solid elements.

11 c
12 c This file uses TrueGrid planes, oriented by eye using trial
13 c and error graphically, to determine an orthonormal section.

14 c Trick there is to adjust surface until walls of proximal neck section 15 c are parallel to global z axis. Use rz to rotate screen to find values,

then use in surface transformation to position CT data for meshing.

17 c 18 c import IGES file containing surface data from CT scan 19 c

20 iges solid1.igs 1 1 mx -18.54 my -16.8 ry 24 rx 22 mz 4.8;

21 c 22 c inner surface

23 c 24 sd 17 sds 9 12;

25 c

5

С

26 c outer surface 27 c

28 sd 18 sds 15 16;

29 c

30 sd 201 plan 31 0. 0. 1.5

32 0.0.1.3

33 sd 202 plan

34 0. 0. 2.5

35 0 0 1

36 sd 203 plan 37 0. 0. -2.3

37 0. 0. -2.3 38 0. 0. 1

38 0 0 1 sd 204 plan

40 0. 0. 3.3

41 0 0 1

42 sd 301 cy 0 0 0 0 0 1 1.35

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```
sd 401 plan
43
                                                                     FIG. 7B
             0.0.0.
44
             0.1.0.
45
46
         С
         c .... adjust mz to position part at cuff on Z-axis;
47
                cuff may be z=[2,2.15]
48
49
         cylinder
50
          12;
51
         1 2 3;
         1234;
52
53
         С
         1.0 1.25
54
         0 180.0 360.0
55
         -2.3 1.5 2.5 3.3
56
57
58
         mseq i 2
         mseq j 29 29
59
60
         mseq k 20 5 5
61
         c .... project top and bottom ends of aorta segment onto orthonormal planes
62
63
64
         sfi;;-2; sd 201
65
         sfi;;-3; sd 202
66
          c .... project top of upper neck segment onto orthonormal plane
67
68
69
          sfi;;-4; sd 204
70
          c .... project bottom of lower neck segment onto orthonormal plane
71
               after radially expanding bottom ring by delta-r=2.0
72
          mbi -1;; -1; x 2.0
73
74
          mbi -2;; -1; x 2.0
75
          sfi;;-1; sd 203
76
          c .... project inner cylinder surface onto aorta luminal surface
77
78
79
          sfi -1; 1 3; 2 3; sd 17
          sfi -1; 1 3; 3 4; sd 17
80
          sfi -1; 1 3; 1 2; sd 17
81
82
          c .... project outer cylinder onto aorta outer wall surface
 83
 84
```

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```
85
         sfi -2; 1 3; 2 3; sd 18
86
         sfi -2; 1 3; 3 4; sd 18
87
         sfi -2; 1 3; 1 2; sd 18
88
89
         c .... project theta=0/360 seam onto a plane to facilitate merging
90
91
         sfi 1 2; -1;; sd 401
         sfi 1 2; -3; ; sd 401
92
93
94
95
         c ... --- slidesurface definition with TPEG body ---
96
97
         orpt + 0.0.3.0
98
         sii -1; 1 3; 3 4; 5 m
99
100
         c .... +y hemicylinder is material 11; -y is mat 12
101
102
         mti; 12; 24; 11
         mti; 23; 24; 12
103
104
105
         c .... rigid material for aneurysm sac
106
107
         mti; 13; 12; 13
108
         c .... Boundary Conditions
109
110
              * fix proximal end only in z
111
112
         bi;;-4; dz 1;
113
         c .... adjust mz to position aorta at cuff on Z-axis;
114
115
                cuff may be z=[2,2.15]
116
          lct 1
117
             mz [1.01*2.54] mx 0.7;;
118
          lrep 1;
         endpart
119
120
```

FIG. 7C

MEDICAL DEVICE DEVELOPEMENT.
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FIG. 8A

```
c ****** Slotted Tube Integrated Stent Design Simulation ******
1
2
                      (istent.run)
       С
3
              Stent design analysis & CT-Anatomy simulation
       С
4
5
       c ----- parameter settings -----
6
7
        c .... inike=1 => make nike file; inike=0 => make dyna file
8
       c .... imodel = 0 => full 3 segment model with interconnects
9
       c = 1 \Rightarrow 3-crown segment only
10
                = 2 \Rightarrow 6-crown segment only
11
              = 3 => 12-crown segment only
        c \dots isym = 0 \Rightarrow full 360 deg model
12
              = 1 => symmetric model
13
        c .... isim_mode: type of simulation
14
15
              = 1: => radial force to R f = 80% R 0, restoring stress mat'l
              = 2: => flat plate force, restoring stress mat'l
16
17
              = 3: => predelivery compression to 12 F, loading stress mat'l
       С
18
              = 4: => initial expansion
       С
              = 5: => frequency analysis
19
20
              = 6: => anatomy deployment
        c .... refine = X => add X elements via mseq in each direction
21
                    of the cross section
22
23
24
        c !!! warning - only 1st 8 characters of variable unique !!!!
25
26
        parameter inike 1;
27
        parameter imodel 2;
28
        parameter isym 0;
29
        parameter isim mode 6;
30
        parameter refine 1;
31
32
        para Tighten [0.9];
                             c helps 'tighten' or stiffen spline
33
                       c range (0.5,1) (probably should not change)
34
35
        c ----- parameter settings -----
36
37
        c .... design parameters
38
        c Note: Adjust specified OD for each segment considering the wall thickness
39
40
              for that segment so that ID's match in a consistent way for the
41
              tube blank from which they were cut.
        С
42
43
        c Upper segment --- 3 crowns
44
        c Middle segment -- 6 crowns
45
        c Lower segment --- 12 crowns (could be conical)
46
47
        c Parameters for 3-crown segment
48
49
        para
```

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FIG. 8B

```
50
         RCyl3 [29*0.5/25.4]
           dCIA3 [-.00] c delta of center of inner arc for 3 crown segment (-:0)
51
                         c delta of center of outer arc for 3 crown segment (0:+)
52
           dCOA3 [0]
           CW3 [.020]
                         c Circumferential width of segments for 3 crowns
53
           RW3 [.018] c Radial width for 3 crowns
54
55
           NRA3 [.0195] c normal radius of smaller cylinders (arcs)
56
                    c for 3 crowns
57
           Ht3 [1.048] c distance from center of upper arcs
58
                    c to center of lower arcs for 3 crowns
59
           NLegEl3 [12]; c number of elements along the leg
60
61
        c Parameters for 6-crown segment
62
63
        para
           RCyl6 [29*0.5/25.4] c outside radius for 6 crown segment
64
                        c delta of center of inner (smaller) arc for 6 crown segment (-:0)
65
           dCOA6 [0.005] c delta of center of outer (larger) arc for 6 crown segment (0:+)
66
           CW6 [.020] c Circumferential width of segments for 6 crowns
67
           RW6 [.018] c Radial width for 6 crowns
68
69
           NRA6 [.0195] c normal radius of smaller cylinders (arcs)
70
                    c for 6 crowns
                         c distance from center of upper arcs
71
           Ht6 [.310]
72
                    c to center of lower arcs for 6 crowns
73
           NLegEl6 [12]; c number of elements along the leg
74
75
        c Parameters for 12-crown segment
76
77
        рага
                           c delta of center of inner arc for 12 crown segment (-:0)
78
           dCIA12 [0]
                             c delta of center of outer arc for 12 crown segment (0:+)
79
           dCOA12 [0]
80
           CW12 [.008]
                             c Circumferential width of segments for 12 crowns
                             c Radial width for 12 crowns
81
           RW12 [.008].
82
           NRA12 [.006]
                              c normal radius of smaller cylinders (arcs)
                       c for 12 crowns
83
84
                            c distance from center of upper arcs
           Ht12 [.164]
                      c to center of lower arcs for 12 crowns
85
                      c (measured along the leg, not necessarily in
86
87
                      c the z direction)
88
           c first outside radius for 12 crown segment (near other segments)
89
           RCyl12_1 [22*0.5/25.4]
90
           c second outside radius for 12 crown segment (bottom)
91
           RCY112 2 [20*0.5/25.4]
92
93
           NLegEl12 [10]; c number of elements along the leg
94
95
        c Interconnects
96
97
        c Upper interconnects
98
```

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```
99
        para
                                                                       FIG. 8C
        c HIUp [.10]
100
                         c height of interconnect
           HIUp [.20]
                          c height of interconnect
101
           FRUp [.016] c fillet radius for blend
102
           ICWUp [.010] c circumferential width
103
          IRWUp3 [.016] c radial width at 3-crown end
104
           IRWUp6 [.016]; c radial width at 6-crown end
105
106
107
        c S-interconnects
108
109
        para
           SIVer [.03]
                         c vertical distance between upper or lower arc centers
110
           SIVer [.06]
                         c vertical distance between upper or lower arc centers
111
                    c also the distance from the vertical mid-line to
112
                    c the first arc center
113
114
           SIHor [.0125] c horizontal distance between upper two or
115
                    c lower two arc centers
           SIr [.008] c arc radius
116
           SIrO [%SIr+%ICWUp/2] c outer radius
117
           SIrI [%SIr-%ICWUp/2]; c inner radius
118
119
120
        c Lower interconnects
121
        c HILr [.071] c height of interconnect
122
           HILr [.142] c height of interconnect FRLr [.016] c fillet radius for blend
123
124
           ICWLr [.016] c circumferential width
125
           IRWLr6 [.005] c radial width at 6-crown end IRWLr12 [.005]; c radial width at 12-crown end
126
127
128
129
        c .... design parameters =
130
131
        c .... set cylinder ID & OD for compression
132
133
        if (%isim mode.le.3.or.%isim mode.eq.6) then
        parameter ricompcyl [1.1*max(%RCyl3,%RCyl6,%RCyl12_1,%RCyl12_2)];
134
        parameter rocompcyl [1.4*max(%RCyl3,%RCyl6,%RCyl12 1,%RCyli2 2)];
135
136
137
        c .... set cylinder ID & OD for expansion
138
139
        elseif (%isim mode.eq.4) then
        parameter rocompcyl [0.95*(min(%RCyl3,%RCyl6,%RCyl12_1,%RCyl12_2)-%RW6)];
140
        parameter ricompcyl [0.7* (min(%RCyl3,%RCyl6,%RCyl12_1,%RCyl12_2)-%RW6)];
141
142
143
        С
144
        c Materials assignments
145
146
        parameter matst12 3;
147
        parameter matst6 4;
```

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```
148
       parameter matst3 5;
149
       parameter mati126 6;
       parameter mati63 7;
150
151
152
       if (%isim mode.eq.1) then
          echo *** Radial Force Simulation ***
153
154
       elseif (%isim_mode.eq.2) then
155
          echo *** Flat Plate Force Simulation ***
       elseif (%isim_mode.eq.3) then
156
          echo *** Predelivery Compression Simulation ***
157
158
       elseif (%isim_mode.eq.4) then
159
          echo *** Initial Expansion Simulation ***
       elseif (%isim_mode.eq.5) then
160
161
          echo *** Natural Frequency Analysis ***
       elseif (%isim mode.eq.6) then
162
163
          echo *** Anatomy Deployment Simulation***
164
       else
          echo !!! ERROR: illegal isim mode !!!
165
166
          interrupt
       endif
167
168
169
        c ----- analysis options -
170
        title human-size stent anatomy deployment
171
            *** DYNA3D Analysis Options ***
172
        С
173
174
        if (%inike.eq.0) then
175
        echo Making DYNA3D input file
176
        dyna3d
177
         dynaopts
178
         term 2.0e-4
179
         plti 1.e-4
180
         prti 5.0e-6
181
182
        c .... DR options
183
184
        c itrx 500
185
        c tolrx 1.0e-6
        c drdb
186
187
188
        c .... thermal effects option - temp from load curve 1
189
190
        if (%isim_mode.ne.5) then
191
        teo 1
192
        endif
193
        С
194
        tssf 0.0
195
196
        c print initial time step size
```

FIG. 8D

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```
197
        С
                                                                       FIG. 8E
198
        c prtflg 1
199
200
        c .... turn off (0) or on (1) SAND database flag
201
202
        edsdf 0
203
204
        nrest 90000
205
         nrunr 95000;
206
207
        c .... DYNA3D stent to compression cyl
208
209
        sid 1 dni
210
        c sfif
211
        c mfif
212
        pnlts 1.0e-0
213
        pnltm 1.0e-0
214
215
        С
216
        c .... DYNA3D tied interface to interconnects if multisegment
217
218
        if (%imodel.eq.0) then
219
        sid 2 tied
220
221
        endif
222
223
        c .... end DYNA3D commands
224
225
        endif
226
        С
227
            *** NIKE3D Analysis Options ***
228
229
        if (%inike.eq.1) then
230
         echo Making NIKE3D input file . . .
231
       . nike3d
232
         nikeopts
233
234
        c .... temperatures follow load curve 1
235
            ** manually add tref=1.0 on matl 2 control card cols 26-35 **
        С
236
        С
237
         teo 1
238
239
        if (%isim mode.eq.5) then
240
         anal dyn
241
         neig 20
242
         shift 69
243
         iplt 1
244
         nsbrr 1
245
         stifcore 1
```

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```
246
          bfgscore
                                                             FIG. 8F
247
          bwmo new
248
        c element constitutive data incore
249
250
251
          bfor 10
252
          sfor 10
253
          bef 11
254
255
        c .... linear solver
256
         Isolver fissle
257
258
259
        elseif (%isim_mode.ne.5) then
260
261
        c .... time step analysis
262
263
          nstep 100
          delt 0.0100
264
          anal stat
265
266
        c .... step tol of 1e-2 is OK for predel compression
267
268
        if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
269
          dctol -1.0e-3
270
         elseif (%isim_mode.eq.3) then
271
          dctol -1.0e-2
272
         endif
273
274
         c .... max iterations per stiffness reform
275
276
277
          nibsr 20
278
         c .... max stiffness reforms per step
 279
 280
 281
           msrf 20;
         if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
 282
 283
 284
         elseif (%isim mode.eq.3.or.%isim_mode.eq.4) then
 285
           iprt 25
 286
         endif
 287
           iplt 1
 288
           nsbrr 1
 289
           stifcore 1
 290
           bfgscore
 291
           echo Bandwidth minimization ACTIVATED with "NEW" option
 292
 293
         c element constitutive data incore
 294
```

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```
295
                                                                  FIG. 8G
296
          bfor 10
          sfor 10
297
          bef 11
298
299
        c .... linear solver
300
301
         Isolver fissle
302
303
        c .... solid element stent contact surface
304
305
        sid 1 sv
306
307
        if (%isim mode.eq.1) then
308
309
        c .... below changed for sharp-edge laser-cut stent
310
311
312
          pnlt 1.0e-3
         elseif (%isim_mode.eq.2) then
313
         pnlt 0.01
314
         elseif (%isim_mode.eq.3) then
315
316
         c .... essential to cut penalty for laser-cut stent predel compression
317
318
319
         pnlt 0.001
         elseif (%isim_mode.eq.4) then
320
          pnlt 1.0e-3
321
322
         c iaug 1;
         endif
 323
 324
 325
         c .... end block for time step only analysis
 326
 327
 328
         endif
 329
         c .... slidesurface between interconnects and segments
 330
 331
 332
         sid 2 tied
 333
 334
         c .... slidesurface between stent and aortic wall
 335
 336
         if (%isim mode.eq.6) then
 337
         echo *** Add activation time of 0.5 to slidesurface 2 ***
 338
 339
         sid 3 sv
 340
         endif
 341
 342
          c .... NIKE3D shell geometric stiffness (HL only)
 343
```

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```
344
      ° C
                                                                     FIG. 8H
345
        segs 1;
346
        c .... end NIKE3D section
347
348
        С
349
       endif
350
351
        c .... symmetry planes (omit for freq analysis)
352
353
        if (%isim mode.ne.5) then
354
        if (%isym.eq.1) then
355
356
        c .... Symmetric Model
357
358
        c plane 1
        c 0.0 0.0 0.0
359
360
        c [-sin(60)] [-cos(60)] 0.0
361
           0.0005 symm;
362
        c plane 2
363
        c 0.0 0.0 0.0
364
        c [-\sin(60)][\cos(60)]0.0
365
            0.0005 symm;
366
        С
367
        else
368
        c .... symmetry planes to remove rigid body modes for full model
369
370
371
        plane 1
         0.0 0.0 0.0
372
373
         1.0 0.0 0.0
374
          .0005 symm;
375
        plane 2
376
         0.0 0.0 0.0
         0.0 1.0 0.0
377
378
          .0005 symm;
379
        endif
380
        endif
381
        С
382
383
        if (%inike.eq.0) then
384
        c .... Load Curves for DYNA3D **** ADD DR FLAG TO INPUT FILE ****
385
386
387
        if (%isim_mode.eq.1) then
388
        c .... radial force
389
390
391
        lcd 1
           0.000E+00 1.000E+00
392
```

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```
393
          7.500E-03 2.250E+02
                                                                  FIG. 8I
394
          1.000E-00 2.250E+02;
395
       elseif (%isim_mode.eq.2) then
396
397
       c .... flat plate compression, lcd 1 not used (dummy definition)
398
399
       echo!!! Flat plate not implemented for DYNA3D!!!
400
       quit
401
       elseif (%isim mode.eq.3) then
402
403
404
       c .... predelivery compression strain - 0.87 in. dia compressed to 12F
405
              [check x-displ of stent center node to verify]
406
407
       lcd 1
408
          0.000E+00 1.000E+00
409
          1.000E-02 1.008E+03
410
           1.000E-00 1.008E+03;
411
       elseif (%isim_mode.eq.6) then
412
413
       c .... anatomy deployment
414
            (LC from radial comp)
415
416
       lcd 1
417
          0.000E+00 1.000E+00
418
           7.500E-04 1.000E+03
419
          9.000E-04 1.000E+03
420
           1.500E-03 1.000E+00
421
           1.000E-00 1.000E+00;
422
       endif
423
424
       c .... load curve #2 only used for flat plate compression
425
426
       lcd 2
          0.000E+00 0.000E+00
427
428
          1.000E+00 0.000e-00;
429
       endif
430
431
       if (%inike.eq.1) then
432
       c .... ******* Load Curves for NIKE3D *******
433
434
435
       if (%isim_mode.eq.1) then
436
437
       c .... radial force
438
439
       lcd 1
440
           0.000E+00 1.000E+00
441
           1.000E+00 3.000E+02;
```

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```
442
        elseif (%isim mode.eq.2) then
                                                                          FIG. 8J
443
444
       c .... flat plate compression, lcd 1 not used (dummy definition)
445
446
        lcd 1
447
           0.000E+00 1.000E+00
448
           1.000E+00 0.000E+00;
449
        elseif (%isim mode.eq.3) then
450
451
        c .... predelivery compression strain - 0.87 in. dia compressed to 12F
              [check x-displ of stent center node to verify]
452
453
        С
454
        lcd 1
455
           0.000E+00 1.000E+00
456
           1.000E+00 1.008E+03;
457
        elseif (%isim mode.eq.4) then
458
        c .... initial expansion strain - 4/5 mm OD to 15/27 mm OD
459
460
              [check x-displ of stent center node to verify]
461
        С
462
        lcd 1
463
        c .... thermal load (activate TEO above)
           0.000E+00 1.000E+00
464
465
           1.000E+00 -1.008E+03;
466
        c .... prescribed displacement
467
           0.000E+00 0.000E+00
468
           1.000E+00 1.000E-01;
        С
469
        elseif (%isim_mode.eq.5) then
470
471
        c .... must define load curve since TEO active even if unused for freq
472
473
474
        c .... initial expansion strain - 4/5 mm OD to 15/27 mm OD
475
              [check x-displ of stent center node to verify]
        С
476
        С
477
        lcd 1
478
        c .... thermal load (activate TEO above)
479
           0.000E+00 1.000E+00
480
           1.000E+00 -1.008E+03;
481
        elseif (%isim mode.eq.6) then
482
483
        c .... anatomy deployment - 0.87 in. dia compressed to 12F
484
        С
485
        lcd 1
486
           0.000E+00 1.000E+00
487
           0.500E+00 5.000E+02
488
           1.000E+00 1.000E+00;
489
        endif
490
        endif
```

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```
491
                                                                   FIG. 8K
492
       c ----- stent parts -----
493
494
       include irss.tg
495
496
       c ----- anatomy parts -----
497
498
       if (%isim mode.eq.6) then
499
500
       c .... convert anatomy data from cm to inch units
501
502
       control
503
       csca [1./2.54]
504
505
       c .... import meshed anatomy data for stent deployment
506
              (this is an aortic stent)
       С
507
       include tpeg.part_ct_aorta3
508
509
       csca 1.0
510
       merge
511
       if (%inike.eq.1) then
512
513
       c .... set material properties for aortic wall
514
515
       include aorta.materials nike
516
       endif
       endif
517
518
519
       c ----- stent materials -----
520
       if (%inike.eq.1) then
521
522
             if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
               include istent.mats_nike_solid
523
524
               echo NiTi model for radial force/flat plate analysis
             elseif (%isim mode.eq.3) then
525
               include istent.mats_compress_nike_solid
526
               echo NiTi model for predelivery compression strain
527
528
             elseif (%isim_mode.eq.4) then
               include istent.mats_compress_nike_solid
529
530
               echo NiTi model for initial expansion strain
531
             elseif (%isim mode.eq.5) then
532
               include istent.mats_nike_freq_solid
               echo NiTi model for frequency analysis
533
             elseif (%isim_mode.eq.6) then
534
535
               include istent.mats_nike_solid
536
               echo NiTi model for anatomy deployment
537
             endif
538
        elseif (%inike.eq.0) then
539
```

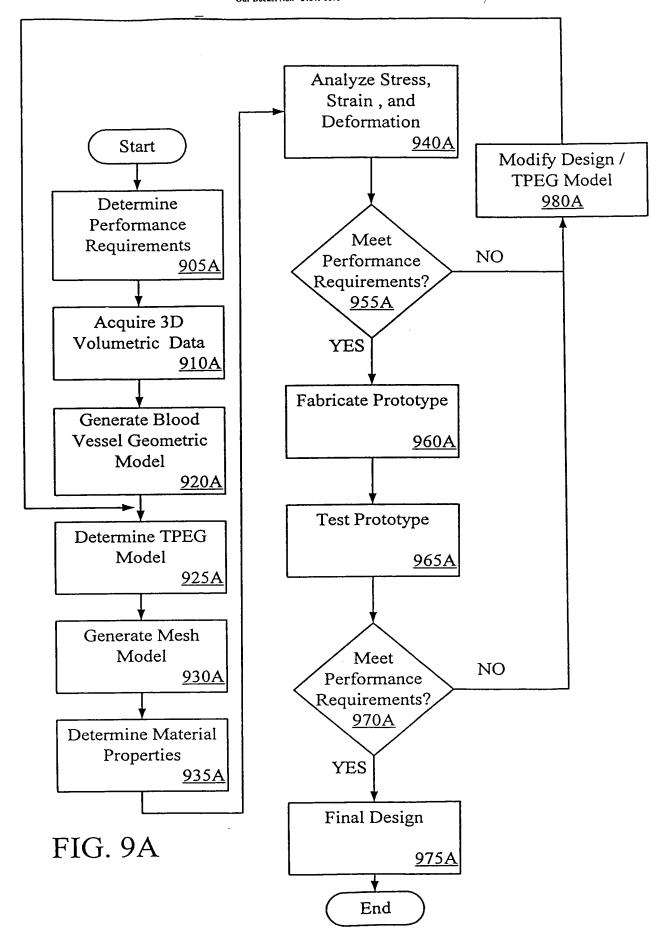
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```
540
            if (%isim_mode.eq.1.or.%isim_mode.eq.2) then
                                                                            FIG. 8L
541
              include istent.mats dyna solid
542
              echo NiTi model for radial force/flat plate analysis
543
            elseif (%isim mode.eq.3) then
544
              include istent.mats_compress_dyna_solid
545
              echo NiTi model for predelivery compression strain
546
            elseif (%isim mode.eq.4) then
547
              include istent.mats_compress dyna solid
548
              echo NiTi model for initial expansion strain
            elseif (%isim_mode.eq.6) then
549
550
              include istent.mats_compress_dyna_solid
551
              echo NiTi model for anatomy deployment
552
            endif
553
      endif
554
555
      c .... cylindrical compression for radial force or predelivery compression
556
557
      if (%isim_mode.eq.1.or.%isim_mode.eq.3.or.%isim_mode.eq.4.or.%isim_mode.eq.6) then
558
559
         if (%isym.eq.1) then
560
           include cylinder.parts sym
561
         else
562
           include cylinder.parts
563
         endif
564
         endif
565
566
      if (%inike.eq.1) then
567
        include cylinder.materials nike
568
      elseif (%inike.eq.0) then
569
        include cylinder.materials dyna
570
      endif
571
572
      stp .0001
573
574
      c .... Constrain stent node(s) in z-direction for time-hist analysis
575
576
      if (%isim mode.ne.5) then
577
      merge
578
579
      c .... nset for 3-segment model
580
      c nset zconstr = 18149 8687 9215 9747 :
581
      c echo ** Bottom 12-crown node list Constrained in Z-translation **
582
583
      c .... nset for 6-crown only
584
      echo ** Bottom 6-crown node list constrained in z-dir **
585
      nset\ zconstr = 14397151448;
586
      b nset zconstr dz 1;
587
      endif
588
      С
```

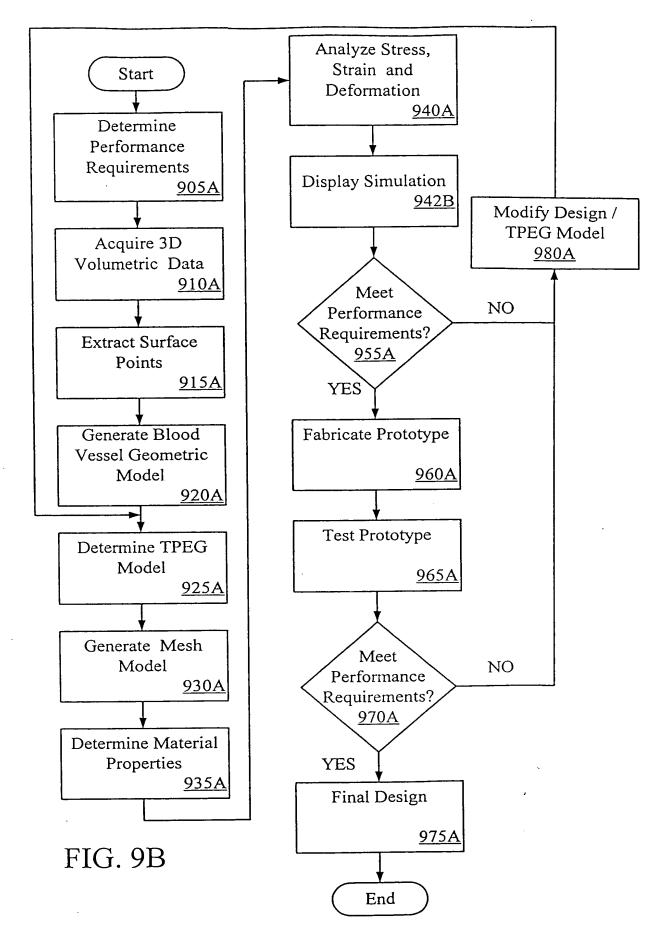
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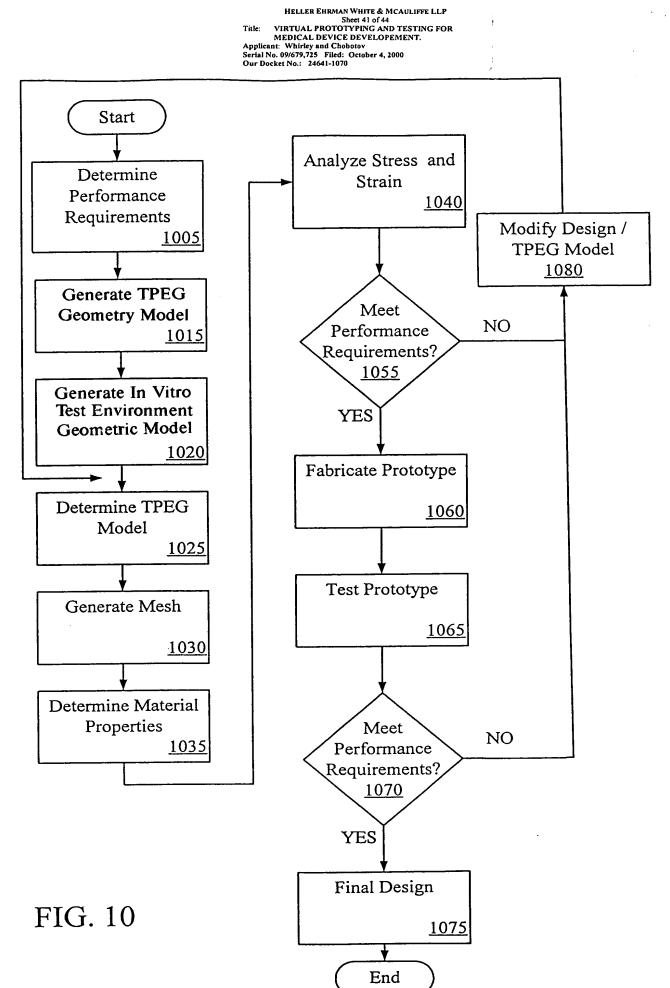
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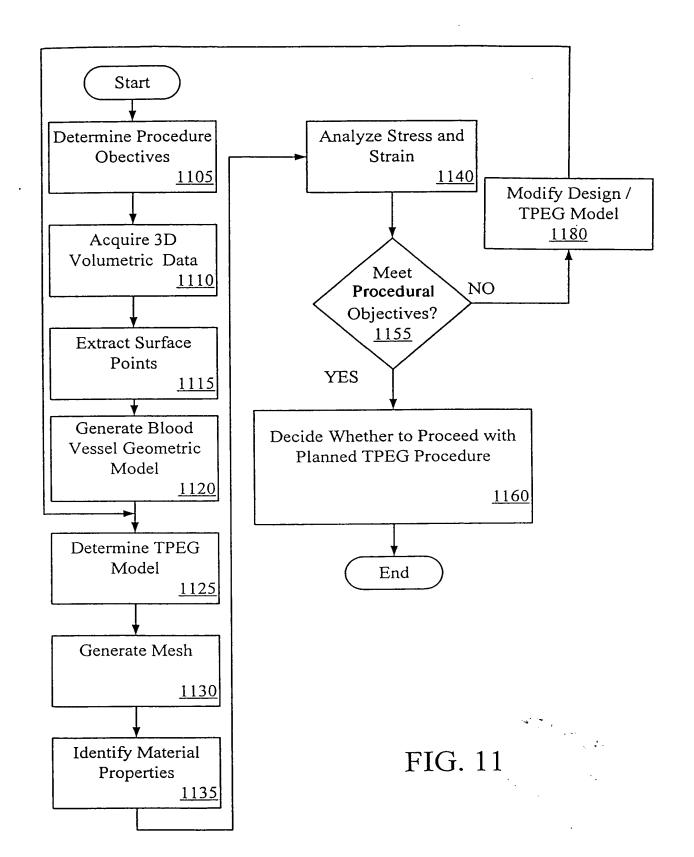




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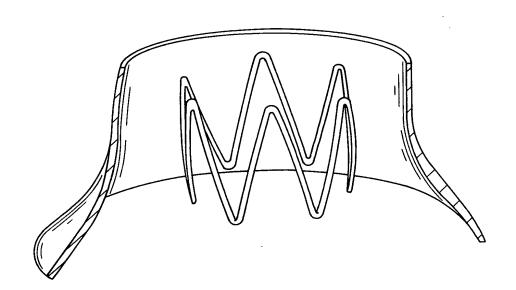


FIG. 12

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FIG. 13

